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08/009,833	01/27/93	ROBINSON H	UMMC91-03A

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EXAMINER	
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ART UNIT	PAPER NUMBER
1813	18

DATE MAILED: 02/21/95

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☒ ~~is extended to run~~ _____ ~~or~~ continues to run 3 months from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 2/6/95 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: none
   Claims objected to: none
   Claims rejected: 1,2,4, 7-14, 17-24

   However;

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because for reasons already of record in paper no. 16 and reasons indicated on attached sheets.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☒ Other attached sheets.

PTOL-303 (REV. 5-89)

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The examiner acknowledges receipt of the after final amendment cancelling claims 3, 5, 6, 15 and 16, amending claim 4 and adding claims 19-24. The after final amendment will be entered.

8. Applicant's arguments filed 2/6/95 have been fully considered but they are not deemed to be persuasive.

9. The rejection of claims 1, 2, 4, 7-14, 17-20, 22 and 23 under 35 U.S.C. §112 first paragraph as the disclosure is enabling only for claims limited to a method of immunizing vertebrates by administering a DNA transcription unit encoding H1 and H7 hemagglutinin antigens is maintained essentially for reasons set forth in paper no. 16, paragraph 18 of the previous office action. Applicant urges that H1 and H7 subtypes are representative of the subtypes which can be used and were not intended to be used with other subtypes. It is the examiner's position that the claims are broadly drawn to infectious agents and influenza. The specification lacks sufficient description of other influenza subtypes which would have the claimed functional features and would be effective in protection against other than the claimed subtypes and strains.

10. The rejection of claims 1, 2 and 4 under 35 U.S.C. §103 as being unpatentable over King is maintained essentially for

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reasons set forth in paper no. 16, paragraph 19 of the previous office action. Applicant urges that King provides no data demonstrating antigenic protection, does not teach or describe inoculation with a gene for an influenza epitope and one of ordinary skill in the art would not expect the construct of King to produce a cytotoxic T cell response. It is the examiner's position that the claims are drawn to a method of immunizing a vertebrate against an infectious viral agent with a DNA transcription unit encoding a desired antigen. King describes a DNA transcription unit (comprising a CMV early promoter sequence and a TPA sequence) with genes encoding the gp120 of HIV. The transcription unit was injected into the muscle of mice and "in turn produced cytotoxic T cells against the gp120 protein.". King appear to meet the limitations set forth in the claims and,

absent evidence to the contrary, one would reasonably expect the immune response to be protective.

11. The rejection of claims 1, 2, 4, 7-14 and 17-24 under 35 U.S.C. §103 as being unpatentable over WO 90/11092 in view of Huylebroeck et al is maintained essentially for reasons set forth in paper no. 16, paragraph 20 of the previous office action. Applicant urges that the vectors of the Huylebroeck et al differ from the claimed invention, there is no teaching supporting the combination of references, WO 90/11092 does not mention influenza and one would not have been motivated to combine reference. It is the examiner's position that the claims are drawn to a method of immunizing a vertebrate against influenza H1 and H7 by administering the DNA transcription unit linked to a promoter region and a carrier, thereby eliciting protective immune responses. The claims are not drawn to specific vectors or promoters or amounts of antigen. As has been previously stated, given the concern and focus in the art on effective vaccine against influenza and the fact that the major response to influence infection is directed to the immunodominant hemagglutinin molecule, one would be motivated to include in the DNA transcription unit the gene for hemagglutinin in a method of delivering polynucleotide into a cell. It would have been expected, barring evidence to the contrary, that the immune responses would be protective.

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